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June 25,200 1

VIA MESSENGER
The Honorable Christine Todd Whitman
Administrator, U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: OPPTS-00274D; Voluntary Children's Chemical Evaluation Program (VCCEP)

Dear Administrator Whitman:

The American Chemistry Council Acetone Panel is responding to the notice published in the December 26, 2000, *Federal Register* (FR) announcing the pilot of the Voluntary Children's Chemical Evaluation Program (VCCEP). A consortium has been formed under the Panel to sponsor acetone CAS No. 67-64-1 under Tier 1 of the VCCEP. Members of the Consortium include The Dow Chemical Company, Celanese, The Goodyear Tire and Rubber Company, Shell Chemical and Sunoco.

We understand that sponsoring a chemical in Tier 1 of the VCCEP pilot means that the Consortium and its member companies have made a Voluntary commitment to provide hazard and exposure data, consistent with the requirements of Tier 1 of the pilot program. The Consortium's start date for acetone data development is on or before December 15, 2001. This date has been chosen to allow Consortium members to attend EPA-sponsored workshops on exposure requirements before undertaking efforts in that area, The Consortium has not yet determined a submission date for Tier 1 information, but will make every effort to develop the Tier I submissions for acetone in a timely fashion and fully expect to do so in 2002.

As recognized in EPA's announcement of the VCCEP pilot, sponsorship commitments are not enforceable agreements or contracts. If for any reason this voluntary initiative will not be undertaken under the Panel, any expressed or implied commitment to Tier I of the VCCEP will devolve to the manufacturers and importers of acetone.

As described further below, acetone has undergone several previous reviews by EPA and others, including a review under the OECD Screening Information Data Set (SIDS) program for which the United States was the sponsor country, These reviews recognize that acetone has low toxicity and is a low priority for further work.

However, because the VCCEP process represents a new paradigm for EPA, the Consortium is sponsoring acetone in order to facilitate a "test" of this new chemical evaluation process. The Panel firmly believes that acetone does not pose a risk to human health, including that of children and prospective parents. This conclusion is strongly supported by the previous reviews. of acetone, as described below.

First, it is important to understand that acetone is widely recognized as having low toxicity and is present *naturally* in the human body as a normal product of fatty acid metabolism. Healthy adult humans have endogenous acetone concentrations up to 10 mg/L, while children and adolescents, because of their higher energy expenditure, typically have higher levels of acetone in their blood. Infants have been found to have naturally occurring acetone blood levels ranging as high as 140 mg/L – 10 times the normal range for healthy adults. Similarly, pregnant women naturally have higher levels of acetone in their bodies as a result of increased mobilization and utilization of free fatty acids by the liver. All human blood levels reported in NHANES (the primary justification for including acetone in the VCCEP) are well within the range normally found in healthy individuals.

Second, as indicated, acetone producers have already sponsored a hazard and safety evaluation of acetone under the OECD SIDS program. The SIDS Initial Assessment Report (SIAR) was approved internationally in July, 1999 and concludes, "The human health and environmental effects of acetone have both been well studied," and acetone is a "a low priority for further work." The SIAR finds that acetone: has "low potential for systemic toxicity;" "showed minimal reproductive and developmental effects in animals exposed either by inhalation or via chinking water;" and "does not pose a neurotoxic, carcinogenic, or reproductive health hazard at the concentrations found anywhere in the environment." The SIAR posits that the "ability of humans to naturally produce and dispose of acetone may to a large degree explain its relatively low toxicity following external exposure to moderate amounts of the vapor or liquid."

Third, the National Toxicology Program (NTP) conducted 90-day studies of acetone administered in the drinking water of mice and rats at concentrations up to 5.0 percent (50.000 ppm) and found only minimal toxicity. After completing these studies, the NTP recommended against conducting chronic toxicity or carcinogenicity studies of acetone because "the prechronic studies only demonstrated a very mild toxic response at very high doses in rodents," and because of "the absence of any evidence supporting the carcinogenic potential for acetone."[1] In other words, no two-year cancer bioassay has been conducted for acetone because NTP concluded chronic toxicity studies are not necessary.

[1] The Screening Information Data Set (SIDS) process an international initial screening and assessment program sponsored by the Organization for Economic Cooperation and Development (OECD), See SIDS Initial Assessment Report (July 1. 1999) pp 2.20, 26-27, and 32, and See National Toxicology Program Toxicity Study of Acetone, "Summary of information on Acetone," NTPTS2 (1989).

Fourth, the World Health Organization (WHO) International Programme on Chemical Safety (IPCS) completed its own assessment of acetone in 1999, and reached essentially the same conclusions as the OECD SIAR and NTP.

In summary, although acetone is well-recognized as having low toxicity and the Consortium agrees with previous assessments that acetone is a low priority for further work, the Consortium has agreed to sponsor acetone under Tier 1 of the VCCEP pilot to facilitate the review of the VCCEP process. The technical contact for this activity is:

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Please contact Ms. Loftus if you have any questions regarding this commitment

Sincerely, yours,

Courtney M. Price,
Vice-President, CHEMSTAR

cc: U.S. EPA, Document Control Office (7407)
Office of Pollution Prevention and Toxics

Steve Johnson, U.S. EPA
Assistant Administrator, OPPTS
Office of Pollution Prevention and Toxics

Charles Auer, U.S. EPA
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